## REMARKS

Claims 1-27 are pending. Claims 1-14 have been examined on the merits, and claims 15-27 are withdrawn pending a decision on whether re-joinder is deemed proper. Claims 2-14, 21-23, and 26 are currently amended.

Information Disclosure Statement

Applicant submits the enclosed information disclosure statement ("IDS") for consideration by the examiner. The IDS is submitted prior to a final office action, and is therefore accompanied by the appropriate fee under 37 CFR 1.17(p).

Paragraph 4

Claims 7-9 have been objected to for failing to end with a period. Claims 7-9 have been amended to correct the informality.

Support for Amendments to the Claims

Further to applicant's remark regarding claims 7-9 above, claims 2-14, 21-23, and 26 have been amended merely to correct matters of format; such amendments do not alter the scope of these claims.

Rejection under 35 U.S.C. § 102(b)

Claims 1-5 and 10 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Dandiker et al. (US 5,425,950). The rejection is respectfully traversed.

Dandiker describes a very different type of tablet to that encompassed by that of claims 1-5 or 10. Dandiker describes a tablet having an outer layer comprising a pH independent hydrophilic polymer and an inner layer or layers each comprising an active ingredient in which the outer layer is gradually removed by a combination of dissolution and erosion following

administration (column 3, lines 17-28). The tablet is designed to provide a pulsed release or delayed sustained release of the active ingredient from the core (column 2, lines 23-24; column 3, lines 3-7). Thus, the entire teaching of Dandiker is directed to preventing premature release of the active agent from the core/inner layers of the tablet.

In contrast, the present invention is directed to providing an oral tablet preparation that allows rapid drug (sumatriptan) release and masks the unpleasant taste of the drug (see specification, page 3, lines 21-31). This is provided in the form of the claimed tablet which comprises a core containing sumatriptan and a rapid-release mantle, free of sumatriptan, which entirely surrounds the core. Such tablets are not described by Dandiker because the polymer containing outer layer of Dandiker is removed only gradually, not rapidly as required by claims 1-5 and 10. Thus, the claimed subject matter is distinguished from Dandiker.

Furthermore, the tablets described in Example 10 of Dandiker, to which the examiner has referred, relate to a three layer tablet construction comprising an inner core surrounded by a hydrophilic polymer layer with an additional external third layer comprising a rapidly disintegrating outer coating comprising the active agent (sumatriptan). This is clearly distinguished from the presently claimed tablet, which requires that the outer layer (i.e. the rapid-release mantle) be free of sumatriptan. Accordingly, it is respectfully requested that the rejection be withdrawn.

Rejection under 35 U.S.C. § 103(a)

Claims 1-5 and 10-14 have been rejected under 35 U.S.C. § 103(a) as not being patentable over Dandiker et al. (US 5,425,950), in view of Lerner et al. (US 2004/0052843). The rejection is respectfully traversed.

It will already be clear from our earlier discussion of novelty that the claimed subject matter differs significantly from that of Dandiker. In particular, the present invention is directed to a different problem to Dandiker. Dandiker is concerned with the provision of pulsed release or delayed sustained drug release profiles, whereas, in contrast, the present invention is concerned with the problem of providing an oral tablet preparation that provides both rapid drug (sumatriptan) release and adequate masking of the unpleasant taste of the drug (see specification page 3, lines 21-31). In all embodiments the Dandiker tablets comprise a core surrounded by a polymer layer which is gradually eroded and is intended to delay the release of the drug, not promote rapid release. The essential teaching of Dandiker is, in fact, opposed to that of the invention and would not have influenced the skilled person to provide a tablet having a rapid-release mantle free of sumatriptan, as required by all claims of the present invention. Thus, the claimed invention cannot be regarded as obvious in light of Dandiker.

For the avoidance of doubt, even Example 10 of Dandiker, to which the Examiner has referred, relates to a tablet in which the main dose of the drug is contained in the core and hence is released in a delayed and/or pulsed fashion. According to the present invention, the drug dose is delivered in its entirety in a rapid manner. Moreover, the outermost layer of the tablet of Example 10 of Dandiker would not provide both the rapid release and taste masking properties required by the invention because the outermost layer of the tablet of Example 10 includes sumatriptan.

The Examiner has suggested that the rapid-release characteristics of the tablets of the invention could have been provided in an obvious manner by combining the teachings of Dandiker with Lerner. However, the tablets of Lerner again differ considerably from those of the present invention to the extent that even if the teaching of Dandiker and Lerner were

combined it would not have caused the skilled person to provide the claimed tablets. In particular, Lerner requires absolutely that the core tablet which contains the drug is sheathed in an *anular* body (see paragraph [0010] and claim 1 of Lerner). Thus, by definition, the tablets described in Lerner have a body, or outer layer, which does not entirely surround the core. This is confirmed in paragraph [0031] of Lerner, which indicates that opposed surfaces of the core tablet are substantially exposed (see also, for example, Example 5). Indeed, Lerner explicitly teaches against use of a smaller inner anular diameter, let alone entirely surrounding the core (see paragraph [0039]) as this would undesirably influence the release of the active from the core. Thus Lerner teaches against the use of a mantle which entirely surrounds the core, as required by the claimed invention.

It will also be appreciated that the construction of the tablets of Lerner leaves part of the drug-containing core exposed, and hence does not provide the optimal levels of taste masking provided by the present invention. Indeed, Lerner advocates tablet constructions for immediate release in which the active is released through the exposed surfaces in the core by dissolution in the saliva (see paragraph [0048]). This provides no taste masking and is totally unsuitable for addressing the problem solved by the tablets of the present invention.

In view of the deficiencies of both Dandiker and Lerner, the claimed subject matter cannot be regarded as obvious in light of those documents. It is respectfully requested that the rejection be withdrawn.

Rejection under 35 U.S.C. § 103(a)

Claims 1 and 5-9 have been rejected under 35 U.S.C. § 103(a) as not being patentable over Dandiker et al. (US 5425950), in view of Lieberman et al. (Pharma. Dosage Forms Vol. 1: tablets, 2nd edition, 1990, pp. 188-189). The rejection is respectfully traversed.

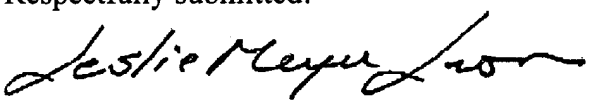
Dandiker is discussed above in the context of rejections asserted under 35 USC §102(b) and 35 USC §103(a); all of applicant's remarks above regarding Dandiker are incorporated by reference and applied to the present rejection. Applicant notes that claims 6-9 incorporate by reference the limitations of claim 1, and thus require that the tablet comprise a mantle which is a rapid release mantle, and that the mantle further be free of sumatriptan.

As noted above, Dandiker fails to provide a tablet having the characteristics of being rapid release and at the same time free of sumatriptan in its outer layer, thereby masking the unpleasant taste of the sumatriptan.. The Lieberman reference fails to teach or even suggest what is lacking in the Dandiker reference. Thus, claims 1 and 5-9 cannot be considered to be obvious in light of Dandiker and Lieberman, and the Examiner's objection should be withdrawn.

## CONCLUSION

Applicant submits that the application is in condition for allowance. Please charge any fees or credit any overpayments to Deposit Account No. 50-1895, Ref. No. 0765-005US1.

Respectfully submitted:



Date: 26 June 2008

Leslie Meyer-Leon
Reg. No. 37,381

IP LEGAL STRATEGIES GROUP P.C.
P.O. Box 1210, 1480 Falmouth Road
Centerville, MA 02632-1210
Telephone: 508-790-9299
Facsimile: 508-790-1955

0765-005US1/31609.doc

Docket No.: 0765-005US1

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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|---|---|---|---|
| APPLICANT: | Craig A. Judy et al. | EXAMINER: | Purdy, Kyle A. |
| SERIAL NO: | 10/598,112 | ART UNIT: | 1611 |
| FILED: | March 5, 2007 | | |
| TITLE: | Compression-coated tablets and manufacture thereof | | |

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicant hereby makes of record the documents listed on the attached modified Form PTO-1449 (submitted in duplicate).

This information disclosure statement is being filed:

- ☐ within three months of the filing date of the national application; or
- ☐ within three months of the filing date of the entry of the national stage, as set forth in 37 C.F.R. §1.491, in an international application; or
- ☐ before the mailing date of a first Office Action on the merits in the above-identified case; or
- ☐ before the mailing date of a first Office action after the filing of a request for continued examination under § 1.114; or
- ☐XXX before the mailing date of any of a final Office action, a notice of allowance, or an action that otherwise closes prosecution, and is accompanied by:
  - ☐ a statement pursuant to 37 CFR §1.97(e); OR
  - ☐XXX the fee pursuant to 37 CFR 1.17(p) and the enclosed Fee Transmittal Form; or
- ☐ before payment of the issue fee, and is accompanied by:
  - ☐ a statement pursuant to 37 CFR §1.97(e); AND
  - ☐ the fee pursuant to 37 CFR 1.17(p) and the enclosed Fee Transmittal Form.

06/27/2008 ABELETE1 00000051 501895 10598112
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"Express Mail" Tracking No.: EV644013211US Date of Deposit: June 26, 2008
I hereby certify that this is being deposited with the Express Mail Post Office to Addressee service under 37 CFR 1.10 on the date indicated above, addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By: Karen A. Herrand
Karen A. Herrand

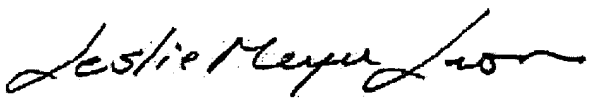
Statement Under 37 CFR 1.97(e)

- ☐ The documents listed on the attached Form PTO-1449 were first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement. A copy of the communication issued by the foreign patent office is enclosed herewith.
- ☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

By submitting the Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist, nor that the information cited in the Statement is considered to be material to patentability as defined in 37 C.F.R. §1.56(b), nor that the information cited in the Statement is prior art as defined by 35 U.S.C. §102. The order of presentation of references is not to be construed as indicative of the importance of the references.

Please charge any additional fees that may be due, or credit any overpayment, to Deposit Account No. 50-1895, Reference No.0765-005US1.

Respectfully submitted,



Date: 26 June 2008

Leslie Meyer-Leon, Esq.
Reg. No. 37,381

IP LEGAL STRATEGIES GROUP P.C.
1480 Falmouth Road
P.O. Box 1210
Centerville, MA 02632-1210
Tel: 508-790-9299; Fax: 508-790-1955

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